Boston Scientific

OPERATOR'S MANUAL

ZOOM® LATITUDE®

Programmer/Recorder/Monitor
Model 3120

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

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INFORMATION FOR USE

Trademark Statement

The following are trademarks of Boston Scientific or its affiliates: LATITUDE, Quick Start, ZIP, ZOOM.

Description and Use

The ZOOM LATITUDE Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM), Model 3140 Zoom Wireless Transmitter (ZWT) and accessories, is a portable cardiac rhythm management system designed to be used with Boston Scientific implantable pulse generators.

Intended Use

The PRM is intended to be used as part of the ZOOM LATITUDE Programming System to communicate with Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the associated product literature for the pulse generator being interrogated.

Intended Audience

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

Essential Performance

In order for the PRM to meet its intended use, it must communicate with Boston Scientific implantable pulse generators. Therefore those functions that pertain to communications with the implanted pulse generator using the telemetry wand are considered essential performance.

Contraindications

The PRM is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator. For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator being interrogated.

WARNINGS

- **Use of unspecified cables and accessories.** The use of any cables or accessories with the PRM or ZWT other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Anyone connecting such cables or accessories to the PRM or ZWT may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.
- **Connector contacts.** Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port).

- **Special committee on radio interference.** Other equipment may interfere with the PRM and ZWT, even if that equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements.
- **Electric shock.** To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source.
- **PRM location.** Do not use the PRM or ZWT adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, check the PRM and ZWT for normal operation in that configuration.
- **PRM and ZWT must remain outside sterile field.** The PRM and ZWT are non-sterile and cannot be sterilized. They must both remain outside the sterile field.
- **Physiological signals.** Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results.
- **Printer parts.** Do not simultaneously touch the patient and the parts inside the printer door.
- **PRM is MR Unsafe.** The PRM and ZWT are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[1]. Under no circumstances should the PRM be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.
- **Modifications.** No modification of this equipment is allowed unless approved by Boston Scientific.

PRECAUTIONS

General

- **Use only appropriate PRM.** Use only the appropriate Boston Scientific PRMs equipped with the appropriate software to program Boston Scientific pulse generators.
- **Wand use.** Use only the Model 6577 Sterilizable Telemetry Wand with the PRM.
- **Stylus use.** Use the stylus supplied with the PRM; the use of any other object could damage the touchscreen. Using the stylus may also improve accuracy.
- **Leakage current.** Although optional external equipment connected to the PRM meets leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment (at least 1.5 m [4.9 ft] away from the patient).

1. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

Preparations for Use

- **Telemetry wand shipped nonsterile.** The Model 6577 Telemetry Wand is shipped nonsterile. If the telemetry wand is to be used in a sterile field, it must be actively sterilized before use or enclosed in a disposable sterile surgical sheath during use.
- **Telemetry wand sterilization.** Remove the telemetry wand from all packaging material before sterilizing it.
- **Electrical and magnetic interference.** Avoid establishing telemetry communication between the PRM and the pulse generator when the PRM or ZWT are in close proximity to monitors, high-frequency electrosurgical equipment, or strong magnetic fields. The telemetry link may be impaired.

Maintenance and Handling

- **Cleaning the PRM.** Do not use an abrasive cloth or volatile solvents to clean any portion of the PRM or ZWT.
- **Disk handling.** Keep disks away from magnets and magnetized objects, including telephones, power-supply adapters, and monitors.
- **Magnet handling.** Do not place a magnet on the PRM or ZWT.
- **PRM use.** The PRM and ZWT are not waterproof or explosion-proof and cannot be sterilized. Do not use them in the presence of flammable gas mixtures including anesthetics, oxygen, or nitrous oxide.
- **Disconnecting the PRM.** To completely disconnect the unit from the power source, first use the On/Off button to turn the system off. Then disconnect the power cord from the back of the unit.
- **PRM accessibility.** Ensure the back of the unit is accessible at all times so that the power cord can be disconnected.

Adverse Effects

None known.

System Features

The PRM uses the Model 6577 Sterilizable Telemetry Wand to communicate with pulse generators and perform the following functions:

- Interrogate and program the implantable pulse generator
- Display records, store patient data, and allow the physician to evaluate alternative prescription modes
- Store patient session data that can be recalled later in the patient session for analysis (for certain applications only)
- Save patient data to the PRM hard drive or to a floppy disk
- Generate printed reports that detail pulse generator functions, stored patient data, and test results
- Perform tests in an electrophysiology (EP) laboratory, in an operating room, in an emergency room, or at a patient's bedside

The PRM also:

- Provides a direct interface between an external stimulator and an implanted pulse generator for programmed electrical stimulation (PES) during EP studies
- May be used to support diagnostic activities pertaining to implanting, programming, and monitoring Boston Scientific implantable pulse generators. The PRM is not intended for use as an ECG monitor or general diagnostic device
- Prints simultaneous real-time surface ECG and telemetered signals (intracardiac electrograms and event markers) using the internal printer/recorder
- Exports saved patient data from the fixed internal hard drive to a removable USB pen drive
- Provides the option to encrypt patient data prior to exporting to a USB pen drive
- Creates PDF report(s) from saved patient data and saves the report(s) to the fixed internal hard drive or to an attached USB pen drive
- Prints PDF report(s) to an external printer connected to the PRM

The PRM is equipped with the following features:

- PRM function keys, including PROGRAM, STAT PACE, STAT SHOCK, DIVERT THERAPY, and INTERROGATE
- Printer/recorder function keys, including paper speed, calibrate, zero to baseline, and paper feed
- Touchscreen with tethered stylus
- Color display screen
- Floppy disk drive
- Internal hard drive
- High-speed thermal printer/recorder using 110 mm (4 in) wide paper
- Connections for slaved stimulation via an external signal source (certain applications only)
- Parallel interface supports optional external printer
- High-level analog outputs
- USB ports used for patient data export to a standard USB pen drive, connection to the 3140 Zoom Wireless Transmitter accessory, connection to an external printer or used for software installation by Boston Scientific personnel

- ZIP™ telemetry, a cordless, hands-free radio frequency (RF) communication option that allows the PRM to communicate with the pulse generator

  NOTE: *To communicate wirelessly using ZIP telemetry, certain pulse generators require the Model 3140 Zoom Wireless Transmitter. For more information, refer to the associated product literature for the pulse generator being interrogated. If ZIP telemetry performance is not satisfactory, use the telemetry wand instead.*

System Accessories

The ZOOM LATITUDE Programming System consists of the Model 3120 PRM and the following accessories:

- Model 3123 Antenna
- Model 3140 Zoom Wireless Transmitter (ZWT)
- Model 3141 USB Cable
- Model 3124 Accessory Bag
- Model 3130 Accessory Kit
- Model 2902 AC Power Cord
- Model 6577 Sterilizable Telemetry Wand
- Model 6627 Patient Data Disks (10)
- Model 6750 Surface ECG Patient Cable
- Model 6979 Printer Paper (4)
- Model 6629 ECG–BNC Slave Cable

To order accessories, contact Boston Scientific using the information on the back cover.

WARNING: The use of any cables or accessories with the PRM or ZWT other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the PRM or ZWT. Anyone connecting such cables or accessories to the PRM or ZWT may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.

Optional External Equipment

Optional external equipment can be used with the PRM. Contact your sales representative to determine what external equipment can be used.

WARNING: Do not simultaneously touch the patient and any accessible connector contacts on the PRM (e.g., USB, parallel port, external VGA monitor, stimulation input, analog output, and expansion port).

CAUTION: Although optional external equipment connected to the PRM meets leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment (at least 1.5 m [4.9 ft] away from the patient).

External Printer

You can use an external printer if it is supported by the pulse generator software application. Use only compatible external printers that have been tested and qualified for use. Refer to the instructions to connect the cable ("Preparing the PRM for Use" on page 6).

PDF reports generated from saved patient data may be sent to an external printer using the Patient Data Management utility. The utility is accessible from the Patient Data Management button on the PRM startup screen.

External VGA Monitor

You can use an external VGA monitor that can synchronize to any horizontal scan frequency.

NOTE: *Equipment connected to the external connections must comply with applicable standards (e.g., IEC/EN 60950-1 for data processing equipment and IEC/EN 60601-1 for medical equipment). Anyone connecting such cables or accessories to the PRM may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.*

Warranty Information

A limited warranty is packaged with the PRM. Unless otherwise agreed, the PRM remains the property of Boston Scientific and Boston Scientific must perform all necessary servicing and repair work. For additional copies, contact Boston Scientific using the information on the back cover.

PREPARING THE PRM FOR USE

Make necessary external connections as directed below.

Prepare the Telemetry Wand

Prepare the 6577 Telemetry Wand for the sterile field by following the sterilization procedures below, or by enclosing the wand in a sterile surgical sheath.

CAUTION: The Model 6577 Telemetry Wand is shipped nonsterile. If the telemetry wand is to be used in a sterile field, it must be actively sterilized before use or enclosed in a disposable sterile surgical sheath during use.

Either ethylene oxide (EO) or steam may be used for active sterilization. Follow the cleaning instructions ("Cleaning the PRM and Accessories" on page 23) before beginning the sterilization process.

CAUTION: Remove the telemetry wand from all packaging material before sterilizing it.

Ethylene oxide (EO) method: Follow the recommendations of the EO sterilization equipment manufacturer and allow the specified aeration time to fully elapse prior to use.

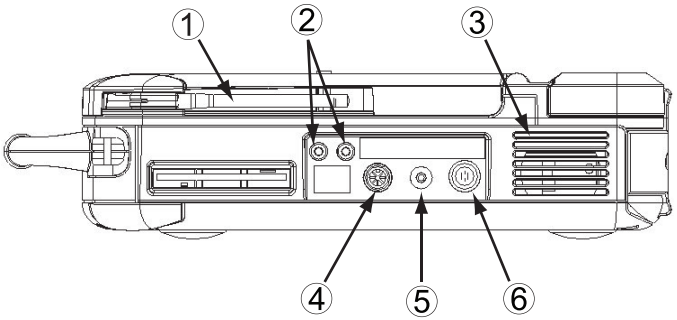
Steam method: Follow customary autoclave procedures for wrapped goods and limit temperature to 132°C (-0°C, +5°C), 270°F (-0°F, +9°F).

NOTE: *The Model 6577 Telemetry Wand has been tested for 25 sterilization cycles and more than this number of sterilization cycles is not recommended. Discard the wand any time surface cracks appear in the plastic and/or the cable discolors or becomes worn, regardless of the number of completed sterilization cycles.*

Make Wand and Cable Connections

For connector locations, refer to the illustrations of the PRM right side, left side, and rear panels (Figure 1 on page 7, Figure 2 on page 8, and Figure 3 on page 8).

1. Make the following connections on the right side of the PRM.



[1] Antenna for ZIP telemetry [2] Stimulator inputs [3] Air intake [4] Analog output channel [5] Telemetry wand connector [6] ECG connector

Figure 1. Right side panel of the PRM

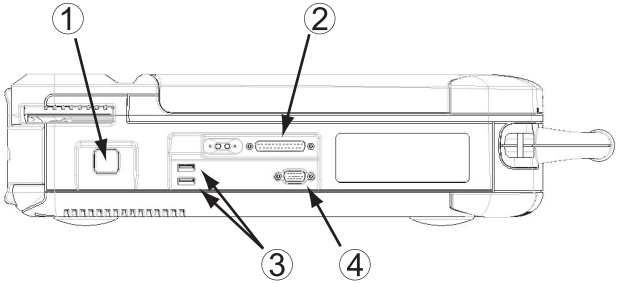
- Connect the telemetry wand to the telemetry wand connector.
- Connect the Surface ECG Patient Cable to the ECG connector. This connection is electrically isolated. Attach the surface electrodes to the patient in a standard three-wire or five-wire configuration.

  NOTE: *The ECG subsystem may be sensitive to high-frequency ambient noise when the ECG inputs are not terminated.*

  NOTE: *The ECG function is intended to be used during patient exams for tests such as pace threshold testing with body-contacting connections.*

  NOTE: *The surface ECG traces may exhibit noise interference if the PRM is in close proximity to high-frequency electrosurgical equipment. For corrective action, refer to the troubleshooting section ("Troubleshooting" on page 27).*
- Connect a controller-stimulator cable to the PRM stimulator input and then into the corresponding terminal on the electrical stimulation source.

2. Make the following connections on the left side of the PRM.



[1] On/Off button [2] External printer connector [3] USB ports [4] External VGA monitor connector

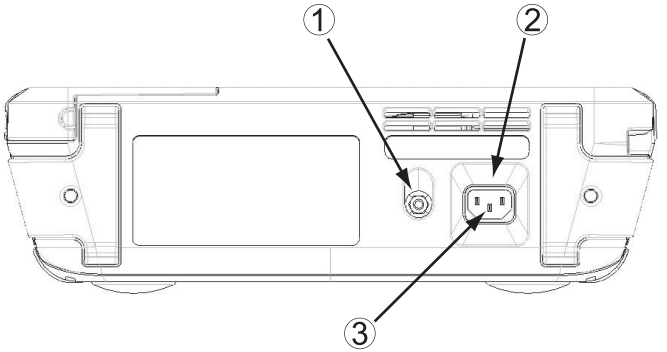
Figure 2. Left side panel of the PRM

- Connect the Model 3141 USB Cable to either USB port.
- Connect the other end of the Model 3141 USB Cable to the Model 3140 Zoom Wireless Transmitter.

NOTE: *To communicate wirelessly using ZIP telemetry, certain pulse generators require the Model 3140 Zoom Wireless Transmitter. For more information, refer to the associated product literature for the pulse generator being interrogated. If ZIP telemetry performance is not satisfactory, use the telemetry wand instead.*

- Use a standard parallel printer or USB cable to attach an external printer to the PRM printer connection.
- Use a standard VGA cable to connect an external VGA monitor or equivalent to the PRM VGA monitor connector.

3. Make the following connections on the rear panel of the PRM.



[1] Equipotential stud [2] AC connector [3] Protective earth terminal

Figure 3. Rear panel of the PRM

- Connect the power cord to the alternating current (AC) connector on the rear panel of the PRM.

- Use the equipotential stud connection to equalize the PRM's galvanic potential with other electrical equipment. Using this terminal to provide equalization may reduce electrical noise problems and the possibility of indirect leakage currents between the PRM and other electrical equipment.

CAUTION: Ensure the back of the unit is accessible at all times so that the power cord can be disconnected.

- Plug the power cord into the appropriate AC outlet.

WARNING: To avoid the risk of electric shock, only connect the PRM to a grounded/earthed power source.

WARNING: Do not use the PRM or ZWT adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, check the PRM and ZWT for normal operation in that configuration.

4. Start the PRM.
   - Raise the screen to a comfortable viewing angle.
   - Press the On/Off button.
   - Wait for the startup screen to appear.

NOTE: *During PRM startup, observe the screen for any messages. If an error message appears, write a detailed description of the error and contact Boston Scientific using the information on the back cover.*

Prepare for ZIP Telemetry

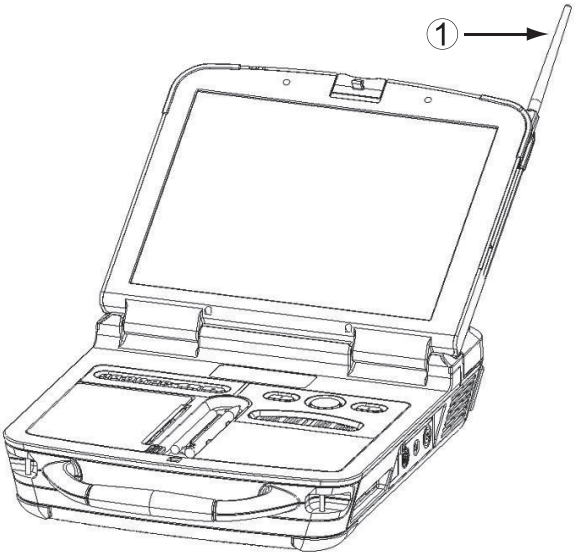
NOTE: *The ZIP telemetry feature is not available for all pulse generators. For more information, refer to the associated product literature for the pulse generator being interrogated.*

1. For pulse generators that use the 3140 Zoom Wireless Transmitter to communicate using ZIP telemetry:
   a. For optimum ZIP telemetry communication, position the ZWT so that it is no further than 3 m (10 ft) from the pulse generator and no closer than 7.6 cm (3 in) from the PRM.
   b. Remove obstructions between the ZWT and the pulse generator.

NOTE: *Repositioning the ZWT further away from the PRM may improve ZIP telemetry performance. If ZIP telemetry performance is not satisfactory, use the telemetry wand instead.*

2. For pulse generators that do not use the 3140 Zoom Wireless Transmitter to communicate using ZIP telemetry:
   a. Raise the antenna on the PRM to its upright position.
   b. For optimum ZIP telemetry communication, position the PRM antenna within 3 m (10 ft) of the pulse generator.
   c. Remove obstructions between the PRM and the pulse generator.

NOTE: *Reorienting the PRM antenna or repositioning the PRM may improve ZIP telemetry performance. If ZIP telemetry performance is not satisfactory, use the telemetry wand instead.*



[1] Antenna

Figure 4. Antenna in the upright position

USING THE PRM

Startup Screen

The PRM has a touchscreen and a tethered stylus allowing you to select items such as buttons, checkboxes, and tabs that are displayed on the screen. Only one item can be selected at a time.

CAUTION: Use the stylus supplied with the PRM; the use of any other object could damage the touchscreen. Using the stylus may also improve accuracy.

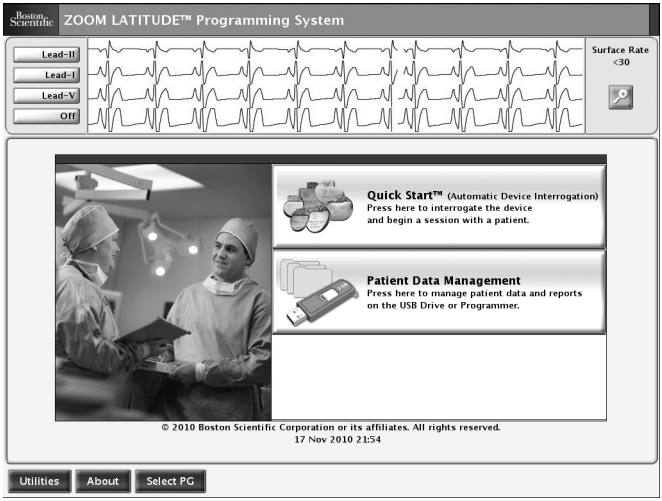


Figure 5. Startup screen

When the PRM is powered On, the startup screen is displayed and contains the following information:

- The ECG Display, which shows four ECG traces for patient diagnosis
- The Surface Rate, which displays the ventricular rate of the patient
- The Details button, which expands the ECG Display to a full screen
- The Quick Start® button, which is an automated method for starting the appropriate application
- The Patient Data Management button, which allows exporting, printing, reading, or deleting patient data and/or reports on an attached USB pen drive or the PRM hard drive
- The Utilities button, which allows access to PRM information and setup functions prior to accessing the application software
- The About button, which allows the user to view, print, and save the PRM configuration information (applications installed on the PRM and their associated version numbers)
- The Select PG button, which allows the desired PG (pulse generator) application software to be selected and started
- The date, time, and PRM information, which are located at the bottom, center area

Changing Parameter Values

The screens for many of the features contain parameter information that can be changed via either a palette window or a keyboard window.

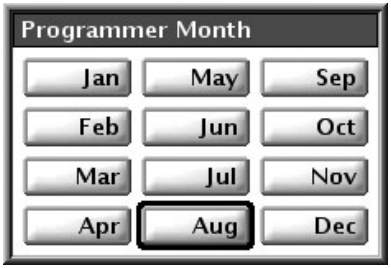


Figure 6. Palette window

- Palette window—To change a parameter value, first select the appropriate parameter's value box. A palette window will appear. Select a value from the palette window by touching the desired value; the window will automatically close when a selection is made. To close a window without making a selection, touch the screen outside the window.

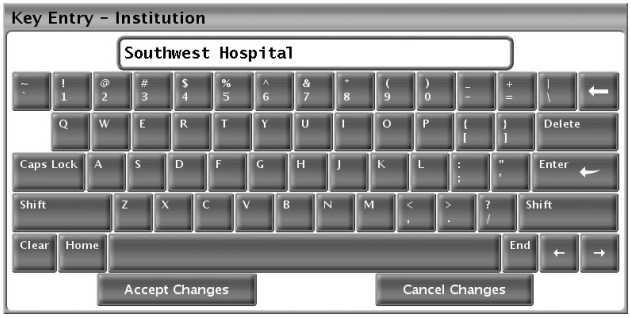


Figure 7. Keyboard window

- Keyboard window—Some screens display value boxes that require unique data to be entered, typically from a keyboard window. To enter data from a keyboard window, first select the appropriate value box. A keyboard window will appear. Touch the first character of the new value; it will appear in the data-entry box in the graphic keyboard. Continue until the entire new value appears in the box. To delete one character at a time, starting with the last character, select the left arrow key on the graphic keyboard. Each time the left arrow key is selected, a character will be deleted in the box. To cancel any deletions or additions just made, select the Cancel Changes button on the graphic keyboard. When all the appropriate characters have been selected, select the Accept Changes button on the graphic keyboard.

  NOTE: *If, when the keyboard window initially appears, it contains data in the data-entry box, select the Clear button on the graphic keyboard to delete all the characters in the data-entry box.*

Copy Button

On those screens that contain a Copy button, you can simply copy parameter values from one screen to another. Select the Copy button. A window will appear with a Copy From column and a Copy To column, with buttons below the columns. Select the desired buttons in both columns, and then select the Copy button.

To program the pulse generator with the copied values, follow the instructions in the associated product literature for the pulse generator being interrogated.

NOTE: *If additional parameters require reprogramming, repeat the copy instructions. Multiple parameter changes can be programmed at one time using batch programming.*

ECG Display

The ECG Display shows surface ECG signals without pulse generator interrogation when the surface ECG patient cable is connected to the PRM and the electrodes are attached to the patient. (However, if a report is being printed, the surface ECG does not display).

NOTE: *The surface ECG may be printed on the internal printer/recorder; press any speed key on the left-side keypad to record a surface ECG.*

The PRM can display four surface traces of up to six limb leads or one chest lead. The top displayed lead will be annotated with the pacing spike marker if that feature is selected. To display the pacing spike markers correctly, the Lead II electrodes must be connected to the patient regardless of which lead is displayed. The Surface Rate will display the ventricular rate as the trace runs.

NOTE: *The ECG functionality of the PRM is intended to support diagnostic activities pertaining to implanting, programming, and monitoring Boston Scientific implantable pulse generators. The PRM is not intended for use as an ECG monitor or general diagnostic device.*

WARNING: Operation of the PRM with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results.

To expand the ECG Display to a full screen, select the Details button on the startup screen. Use the following screen buttons to change the values and appearance of the traces:

- Trace Speed—Select the desired speed on the ECG display: 0 (stop), 25, or 50 mm/s
- Trace 1, Trace 2, Trace 3, and Trace 4—Select the lead traces to be displayed
- Gain—Select the appropriate value to adjust the surface gain of the traces that are captured on printouts
- Enable Surface Filter—Select the checkbox to minimize noise on the surface ECG
- Display Pacing Spikes—Select the checkbox to show detected pacing spikes, annotated by a marker on the top waveform

NOTE: *The values as set up on the startup screen will be the defaults used for the application traces. The corresponding values can be changed from the Trace Selections screen while in the application. For detailed application programming instructions, refer to the associated product literature for the pulse generator being interrogated.*

Intracardiac Electrogram

You can display intracardiac electrograms on the PRM screen. Also, you can print both intracardiac electrograms and event markers on the internal printer. For detailed instructions, refer to the associated product literature for the pulse generator being interrogated.

Quick Start Button

The Quick Start button on the startup screen is used to automatically identify and interrogate the implanted pulse generator. Place the telemetry wand over the pulse generator, and select the Quick Start button.

A message window will appear, indicating one of the following conditions, based on the implanted pulse generator:

- Application startup in progress—If the software for the implanted pulse generator is installed on the PRM, the PRM will identify the pulse generator, start the correct application, and automatically interrogate the pulse generator.
- Software not installed—If the software application for the implanted pulse generator is available for the PRM but not installed on it, a message window will appear, identifying the pulse generator and stating that the software is not installed on the PRM.
- Software not available on PRM—If an older model of a pulse generator is identified, a message window will appear, informing the user to use a Model 2035 or Model 2901 programmer to interrogate and/or program the pulse generator. The model number of the software module or application will also be identified.
- PG not identified—If a non-Boston Scientific pulse generator or one of certain older models of Boston Scientific pulse generators is implanted, a message window will appear, notifying the user that the wand is out of range, telemetry noise is present, or the pulse generator is not identified.

To access the demonstration (DEMO) mode (or the Read Disk feature, which is available in some applications), use the Select PG button located on the toolbar below the startup screen to choose the pulse generator family instead of using the Quick Start button.

Patient Data Management Utility

Saving patient data to the USB pen drive is a two-step process: (1) The PRM allows you to save pulse generator data to the hard drive or a removable floppy data disk. (2) Data saved to the hard drive can then be transferred to a removable USB pen drive.

If a floppy disk is not inserted in the PRM disk drive, any disk operations initiated within any application will be performed on space allocated on the

PRM hard drive. Data saved to the hard drive can then be exported to the USB pen drive through the Export Data feature of the Patient Data Management utility, accessible from the PRM startup screen.

Patient Data Management Features

The Patient Data Management utility allows you to export, transfer, print, read, and delete patient data. On the Startup screen, select the Patient Data Management button to access these features.

Privacy Notice: By exporting data from the PRM, you are assuming responsibility for the privacy and security of that data. Printing, storing, transferring, reading, and deleting of patient data must be performed in compliance with applicable data privacy and security laws. Using the available secure export methods is recommended.

NOTE: *For information about PDF functionality available with the pulse generator being interrogated, refer to the associated product literature.*

Export Data

Patient data on the PRM hard drive can be exported to a USB pen drive.

1. Select the Export tab on the Patient Data Management interface. The system displays a list of patient records currently saved on the PRM hard drive.
2. Select the patient records you want to export. You can select all patient records by selecting the Select All button, or select specific patient records by selecting the checkbox next to a patient's name. You can also undo your selections by selecting the Deselect All button.
3. Select the reports you want to export. The selected reports are created as a PDF file from the data for each selected patient.

   NOTE: *Selecting a report is not required to export patient data. If you want to export patient data only, leave the reports selections unchecked and proceed to the next step.*
4. Select an export method below.
   a. To initiate export of the selected patient data, select the Export button. Patient data in plain format is neither encrypted nor compressed on the USB pen drive.
   b. To initiate export of the selected patient data with encryption, select the Export with Password Protection button. Password protection encrypts Protected Heath Information on the USB pen drive.

      If a pen drive is being used to store patient data for the first time, the system will prompt you to enter and confirm a password:

      i. Enter and confirm the password. The password must be alphanumeric and contain at least six characters.

      ii. Select the Initialize button.

      If the password does not meet the system requirements, the system displays the Password Creation Failed dialog box and prompts you to try again.

When using a non-Boston Scientific computer (e.g., a clinic PC), enter your password to access encrypted patient data stored on the USB pen drive.

NOTE: *The USB pen drive used to store exported patient data cannot contain both encrypted and non-encrypted patient data.*

5. Do not remove the USB pen drive during the export operation. If the export operation fails for any reason, the system displays an error message prompting you to select Try Again or Cancel.
6. If the storage capacity of the USB pen drive is reached during the export operation, the system displays a message stating that the export failed. Insert another pen drive and select the Try Again button to continue with the export.

Transfer Data

Files can be extracted from the USB pen drive to a PC, and can be viewed, saved, e-mailed, or attached to an Electronic Medical Record.

1. Insert the pen drive into any USB port on the PC and open Windows Explorer.
2. Navigate to the pen drive and locate the folder titled “bsc” (in the root directory of the pen drive). Double-click this folder to access the sub-folders.
3. Select a transfer method below.
    a. To initiate transfer of non-encrypted patient data, copy the patient data to the PC.
    b. To initiate transfer of encrypted patient data, double-click the “ExtractAll.bat” file.
        i. When prompted, enter the pen drive password and choose a destination folder.
        ii. Press the Extract All button to extract all of the files from the USB pen drive to the PC.

Each patient record on the USB pen drive is stored in a folder with the following naming conventions:

- For non-encrypted patient data, the patient folder name appears in this format:
  <last name>-<first name>-<birth date>-<model>-<serial>
- For encrypted patient data, the patient folder name appears in this format:
  <model>-<serial>

The Export Data operation transfers the most recent patient data from the PRM to the USB pen drive. It also moves the patient data from the previous sessions to the “old” subfolder within the same patient folder on the USB pen drive.

Print Data

You can print reports for patient data saved on either the PRM hard drive or an attached USB pen drive.

1. Select the Print tab on the Patient Data Management interface.

2. Select the USB Drive or Programmer option to indicate the location from which you want to print patient records.
3. Select the patient records you want to print. You can select all patient records by selecting the Select All button, or select specific patient records by selecting the checkbox next to a patient's name. You can also undo your selections by selecting the Deselect All button.
4. Select the reports you want to print.
5. Use the Number of Copies button to select the quantity of copies you want to print.
6. Select the Print button to print selected patient records and any associated, selected reports.

Read Data

You can read patient data from the PRM hard drive or the USB pen drive.

1. When you attempt to read data from the PRM hard drive or the USB pen drive, the appropriate application is initiated. If the operation is unable to read the patient data, the system displays a message indicating that the application could not be started in Disk Mode or that the data could not be read from the USB pen drive. You can then select Try Again or Cancel to continue.
2. When the read operation initiates successfully, the system displays a message stating that Protected Health Information is being read from the USB pen drive or the PRM hard drive.

NOTE: *The Read Data feature is unavailable on the following pulse generator applications which do not support reading patient data from removable storage media:* ***2865*** *(CONTAK RENEWAL TR),* ***2880*** *(VIGOR),* ***2881*** *(DELTA/VISTA),* ***2890*** *(PULSAR/DISCOVERY/MERIDIAN/CONTAK TR),* ***2891*** *(PULSAR II/DISCOVERY II/VIRTUS II/INTELIS II),* ***2892*** *(ALTRUA/INSIGNIA I/NEXUS I).*

Delete Data

You can manage the contents of the patient data archive on the PRM hard drive or the USB pen drive using the Delete Data feature.

1. Select the Delete tab on the Patient Data Management interface.
2. Select the USB Drive or Programmer option to indicate the location from which you want to delete patient records.
3. Select the patient records you want to delete. You can select all patient records by selecting the Select All button, or select specific patient records by selecting the checkbox next to a patient's name. You can also undo your selections by selecting the Deselect All button.
4. Select the Delete button to initiate the deletion of selected patient records. The system displays the Delete Confirmation dialog box asking you to confirm that you want to delete the selected patient records. Select the Confirm button to continue with the delete operation, or the Cancel button to cancel the operation.

5. When the delete operation initiates successfully, the system displays a message stating that Protected Health Information is being deleted from the system.
6. Do not remove the USB pen drive during the delete operation. If the delete operation fails for any reason, the system displays an error message prompting you to select Try Again or Cancel.

Saving Episodes from Legacy Pulse Generators

When saving patient episodes from a legacy pulse generator, if a record already exists on the PRM hard drive for that patient, new episodes are added to the patient record. The patient record, however, contains an episode index file which lists only the episodes saved during the most recent patient session.

Therefore, when saving patient episodes from a legacy pulse generator, if a record already exists on the PRM hard drive for that patient, saving patient data will replace the episode index file in the patient record.

When reading the patient record back into the pulse generator application, only the episodes listed in the episode index file are displayed. When exporting the patient record to a USB pen drive, all episodes present in the patient record are exported.

Processing Considerations

- When performing multiple patient follow-ups, be sure to start a new session for each patient through the QUICK START or Select PG options (rather than the application's New Patient option). This will ensure that data saved to the PRM hard drive during the previous session is not lost.
- Be sure to save all pulse generator data to either a floppy disk or USB pen drive before returning a PRM to Boston Scientific, as all patient and pulse generator data will be erased from the PRM when it is returned for service.
- No more than 400 unique patient records may be saved to the PRM. When a pulse generator is interrogated, the PRM evaluates if there is a record on file for this pulse generator, or if a new record needs to be created. If a new record is needed, and the PRM is at the 400 record capacity, the oldest record on file will be deleted to create space for the new patient record.
- Up to 200 episodes can be saved to the PRM hard drive during a session with a patient. Performing the Save All to Disk operation with a patient who has more than 200 episodes will save only the oldest 200 episodes. The system will then notify you that the disk is full and you will need to restart the session and save up to 200 selected episodes.
- If a patient has more than 200 episodes, it is recommended that you perform a selective save operation instead of the Save All to Disk operation.
- With VITALITY applications, ensure a floppy disk is inserted when saving profile data to Disk. Otherwise, the system will not prompt you to insert a floppy disk and the profile data will be lost.

Utilities Button

If desired, before accessing the pulse generator software application, you can select the Utilities button to perform the following actions:

- Change the language displayed—Select the Setup tab.
- Enable ZIP telemetry (if it is approved for use)—Select the Setup tab.
- Modify the PRM clock—Select the Date and Time tab. Select the appropriate date or time value box to change any of the date or time parameters, and then select the appropriate value in the window that displays. (The PRM and pulse generator clocks may be synchronized once the application is accessed.)

About Button

Select the About button to display the About screen. Use the About screen to perform the following actions:

- Change the name of the institution. Select the value box next to "Institution." Refer to detailed instructions for entering new data using the keyboard window (Figure 7 on page 12).
- View the PRM model and serial number information.
- Select the System Information tab and view the PRM system information including the version numbers of the system software and the installed software applications.
- Print the PRM system information (known as the About report). To print the About report, select the type of printer (internal or external), the number of copies, and select the Print button.

  NOTE: *If a USB pen drive is inserted in the PRM when the About report is printed, the report is also converted to a PDF and saved to the USB pen drive.*

Select PG Button

You can manually select the software application rather than using Quick Start. Use this option to access the DEMO mode (or the Read Disk feature available in some applications). You also can use this option to interrogate a pulse generator, but you may find it more convenient to use the Quick Start button described earlier in this manual.

To manually access the desired software application, perform the following steps:

1. Select the Select PG button on the startup screen.
2. Select the applicable software application from the icons that represent the available software applications. Each application communicates with its pulse generator family.
3. Choose the desired option to interrogate the pulse generator or use the DEMO mode. (Some applications also will display the option to read a patient data disk.)

a. To become familiar with the software without interrogating a pulse generator, select the DEMO button; the main application screen will appear and the DEMO logo will appear at the top of the screen. The software application screens displayed during the DEMO mode reflect the features and programmable values of the pulse generator family.

   NOTE: *STAT PACE, STAT SHOCK, and DIVERT THERAPY commands are functional in DEMO mode only if the telemetry wand is positioned over the pulse generator.*

b. To exit the DEMO mode, depending on which application you are using, select the New Patient or Quit options from either the Utilities button or the Exit button in the software application. For more information about these options, refer to the associated product literature for the pulse generator being interrogated.

4. To proceed with an interrogation session, or read data from a patient data disk if available, refer to the associated product literature for the pulse generator being interrogated.

Indicator Lights

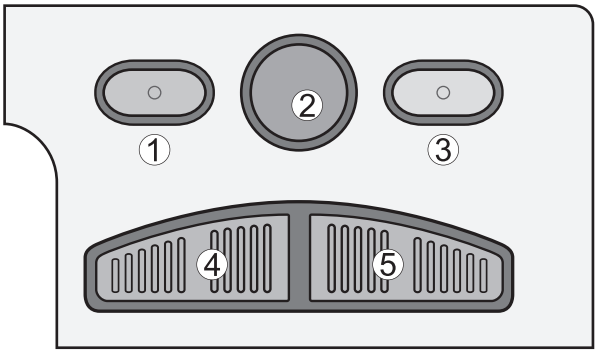
The PRM has indicator lights on the upper left corner, above the screen. The functions are described below.

Table 1. Indicator Lights

Symbol	Indicator Light	Function
	ZIP telemetry	Lit when ZIP telemetry has been established and interrogation or programming of a ZIP-enabled PG is occurring
	Wanded telemetry	Lit when wanded telemetry has been established and interrogation or programming is occurring
	On	Lit when the PRM is On

Keys

General PRM key functions are summarized below. For specific instructions on how to operate the PRM keys and use the telemetry wand, refer to the associated product literature for the pulse generator being interrogated.

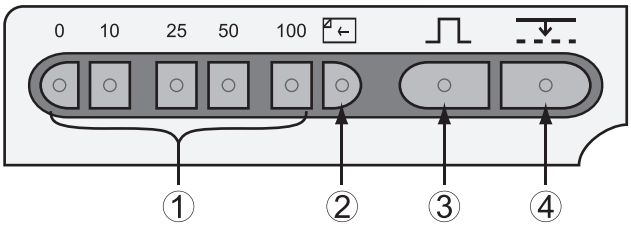


[1] STAT PACE [2] DIVERT THERAPY [3] STAT SHOCK [4] PROGRAM [5] INTERROGATE

Figure 8. Right-side keypad

The following description of the right-side keypad corresponds to the labels in the illustration (Figure 8 on page 21). The PRM must be in telemetry communication with the pulse generator for these functions to be available.

- [1] Press STAT PACE to initiate emergency bradycardia pacing at predetermined high-output parameters.
- [2] Press DIVERT THERAPY to divert tachycardia therapy delivery.
- [3] Press STAT SHOCK to initiate the delivery of an emergency maximum energy shock.
- [4] Press PROGRAM to transmit new parameter values to the pulse generator.
- [5] Press INTERROGATE to obtain information stored in the pulse generator memory.



[1] Speed keys [2] Paper-feed key [3] Calibration key [4] Baseline Key

Figure 9. Left-side keypad

The following description of the left-side keypad corresponds to the labels in the illustration (Figure 9 on page 21).

- [1] Press the speed keys to specify the paper speed for the internal printer/recorder. The printout will show the date and time, lead(s) being printed, gain setting, chart speed, and filter setting. To stop the printer/recorder, press the speed key labeled “0” (zero).

- [2] Press the paper-feed key to scroll the printer paper on the internal printer/recorder.
- [3] Press the calibration key to cause the internal printer/recorder to print a 1-mV calibration pulse.
- [4] Press the baseline key to force the trace back to the baseline after a defibrillation shock.

MAINTENANCE

Loading the Paper

The internal printer/recorder uses thermosensitive printing paper that is 110 mm (4 in) wide. To order Model 6979 printer paper refills, contact Boston Scientific using the information on the back cover.

Use the following procedure to load paper into the internal printer/recorder:

1. Open the printer door.
2. If any sheets from the previous paper pack remain but did not feed, remove them and rotate the roller with clean fingertips to remove any small pieces of paper still under the printhead.
3. Remove any packaging that might be present.
4. Orient the pack such that the pagination mark (which is the small black box that is visible inside the pack if you lift up the top sheet of paper) is located nearest to the front of the PRM. (For a visual of how to orient the paper, refer to the paper liner inside the PRM.) Insert the pack into the printer/recorder.

   NOTE: *You must use paper with pagination markings or the paper will not paginate properly.*
5. Unfold one sheet of paper, and allow the unfolded sheet to lie flat across the well of the stylus.
6. Close the printer door completely. The printer/recorder automatically will begin the paper-loading sequence and will stop at the first pagination mark after paper is detected. If the paper's edges are wrinkled, let four or five pages feed through the printer to self-align the paper to its proper position.

The printer/recorder is now ready to resume printing.

NOTE: *To clear paper jams, open the printer door and use clean fingertips to both remove the paper and rotate the roller in a clockwise direction.*

WARNING: Do not simultaneously touch the patient and the parts inside the printer door.

For information regarding loading paper into the optional external printer, refer to the user manual for the external printer.

Thermal Paper Storage

Store the heat-sensitive paper for the internal printer/recorder in a cool, dark environment. Do not attempt to erase the printer/recorder paper. Printed paper will last approximately 30 days under direct fluorescent light. To ensure the

permanence of a patient's record, store the printed paper away from direct sunlight, heat, or fumes from organic compounds. Storage temperatures above 60°C (140°F), sustained exposure to direct sunlight, or exposure to high humidity, acetone, ammonia, alcohols, or other organic compounds may cause the paper to discolor.

NOTE: *If printed reports are to be kept for prolonged periods, you must make a photocopy of the thermosensitive paper as this paper is not intended for long-term retention and will lose legibility over time.*

NOTE: *Contact with adhesive tape or page protectors will fade the printing after 30 days.*

Cleaning the PRM and Accessories

Clean the housing and touchscreen of the PRM with a soft cloth lightly dampened with water, isopropyl alcohol, a 5% bleach solution, or window cleaner.

Clean the ZWT housing with a soft cloth lightly dampened with water, isopropyl alcohol, a 5% bleach solution, or window cleaner. Do not allow any amount of cleaning solution or moisture to come in contact with the USB port.

Clean the printer/recorder with a dry, soft brush to eliminate dust and particles that may accumulate during printing and storage.

Clean the printer roller with an alcohol wipe.

CAUTION: Do not use an abrasive cloth or volatile solvents to clean any portion of the PRM or ZWT.

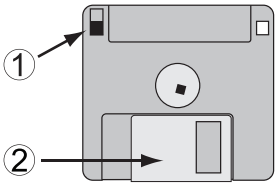
The cables used with the PRM are not sterile when packaged and cannot be sterilized. When necessary, clean the cables with a soft cloth dampened with a mild cleaning solution such as green soap, green soap tincture (U.S. Pharmacopeia), Borax, or alcohol-free hand soap. Use a fresh soft cloth dampened with sterile water to remove residue. Towel-dry or air-dry the cables. DO NOT use an ultrasonic cleaner. DO NOT immerse the cables. When necessary, disinfect the ECG cable using a 2% glutaraldehyde solution (such as Cidex) or a 10% bleach solution.

NOTE: *Discard the ECG cables any time surface cracks appear in the cables and/or the cables discolor, become visibly worn, or if labeling becomes unreadable.*

Clean the sterilizable telemetry wand in the same manner. DO NOT use an ultrasonic cleaner. DO NOT immerse the telemetry wand. DO NOT allow fluid to enter the wand cavity. Refer to "Preparing the PRM for Use" on page 6 for sterilization instructions.

Patient Data Disk

The Patient Data Disk can be used to save patient data. Be certain that the write-protect tab is closed on the disk (Figure 10 on page 24). The write-protect tab must be closed in order to record data to the disk and to print reports. If data cannot be recorded to the disk, check to see that the tab is positioned to cover the hole.

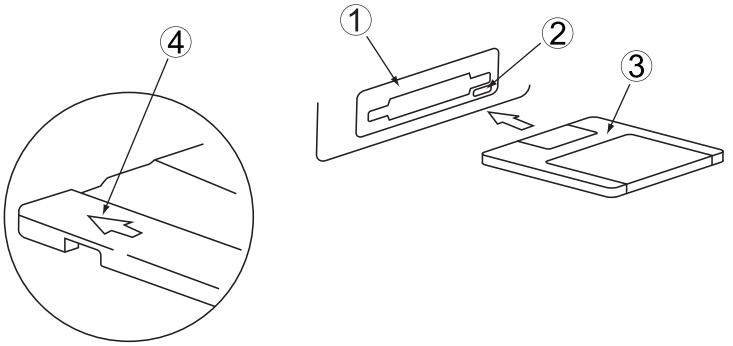


[1] Write-protect tab closed (black tab covering hole) [2] Sliding shuttle

Figure 10. Patient Data Disk

The disk must be inserted with the arrow on the top left side and pointing into the disk drive. Insert a patient data disk firmly into the disk drive on the right side of the PRM until the disk ejection button protrudes (Figure 11 on page 24).

To retrieve the disk, press the disk ejection button.



[1] Disk drive [2] Disk ejection button [3] Patient data disk [4] Arrow on top and pointing to the disk drive

Figure 11. Disk drive on right side of PRM

NOTE: *For complete instructions on using the Patient Data Disk, refer to the associated product literature for the pulse generator being interrogated.*

Caring for Disks

Disks can be damaged easily, making them unusable. To prevent damage to the disks, consider the following:

- Write on labels before applying them to disks.
- Use only a felt-tipped pen to write on a label that is already applied to a disk.
- Keep food and beverages away from disks and away from the PRM.
- Keep disks away from heat or direct sunlight. Disks should be stored at temperatures between 5°C and 60°C (41°F and 140°F).
- Keep disks dry and stored in a dry area (with a relative humidity between 8% and 80%).
- Do not bend disks.

- Do not attach paper clips, staples, or rubber bands to disks.
- Do not try to open the sliding shutter that covers the disks (Figure 10 on page 24).
- Never touch the exposed disk area beneath the sliding shutter.

CAUTION: Keep disks away from magnets and magnetized objects, including telephones, power-supply adapters, and monitors.

Operation and Storage

The PRM and ZWT require special handling. The hard-disk drive and the floppy-disk drive of the PRM must be protected from abusive handling. To protect the PRM and ZWT from damage, refer to the following information:

- Do not turn off the PRM while the drive is accessing data.
- Do not subject the PRM and ZWT to abusive shocks or vibrations.
- When transporting the PRM and ZWT from an outside environment to an inside environment, allow the PRM to acclimate to ambient temperature before use.
- Do not place heavy objects on the PRM surface when closed or when in operation.
- Do not place a magnet on the PRM or ZWT.
- Do not pour or splash liquid into or onto the PRM or ZWT.
- Do not strike, scratch, nick, or otherwise abuse the touchscreen surface.
- Do not disassemble the PRM or ZWT.
- Remove any disks from the drive prior to transporting the PRM.
- Turn off the PRM, close all covers and doors, and put down the antenna prior to transporting the PRM.
- Unplug all external cables and cords prior to transporting the PRM.
- Carefully secure the stylus in its holding tray before closing the PRM's cover.

Operate the PRM, ZWT and accessories within the following conditions:

- Temperature range of 10°C to 35°C (50°F to 95°F)
- Humidity between 25% and 90%

Transport and store the PRM and ZWT within the following conditions:

- Temperatures between -40°C and 70°C (-40°F and 158°F)
- Humidity of 25% to 95%
- Pressure of 50 kPa to 106 kPa (7.252 psi to 15.374 psi)

If the PRM has been stored in cold conditions (less than 10°C [50°F]) or warm conditions (more than 35°C [95°F]), turn it on and let the fan run for at least one hour before use. The PRM and ZWT are capable of continuous operation and will not shut off automatically if they are unused for an extended period of time or if the PRM runs out of paper. Keep the air intake and outlet free from obstruction.

CAUTION: The PRM and ZWT are not waterproof or explosion-proof and cannot be sterilized. Do not use them in the presence of flammable gas mixtures including anesthetics, oxygen, or nitrous oxide.

PRM Storage

1. If using a patient data disk, remove the disk from the disk drive, and store the disk in a safe place. You are responsible for the security of this disk and the associated patient data.
2. Exit the current software application.
3. Press the On/Off button to turn off the power.

NOTE: *Before unplugging the power cord to move the PRM, always exit the software application and press the On/Off button to turn off the PRM.*

4. Unplug the power cord from the wall.
5. Unplug all equipment cables from the back and side panels of the PRM.
6. Lower the screen until the front latch locks in place.

NOTE: *The PRM is not intended to be stored in an upright position (resting on rear panel with handle on top).*

NOTE: *See each accessory's product literature for transport and storage conditions. Ensure each accessory is maintained within the appropriate limits.*

Maintenance Check and Safety Measures

Maintenance Check

Prior to each use, you should perform a visual inspection and verify the following:

- Mechanical and functional integrity of the PRM, ZWT, cables, and accessories.
- Legibility and adherence of the PRM and ZWT labels.
- Startup screen appears a few seconds after you turn on the PRM. (The normal power-up process verifies that the PRM has passed its internal checks and is ready for use.)

The PRM and ZWT contain no user-accessible components and must be returned for replacement of any internal components.

Safety Measurements

National regulations may require that the user, manufacturer, or manufacturer representative periodically perform and document safety tests of the device. If such testing is required in your country, follow the testing interval and extent of testing as regulated in your country. If you do not know the national regulations in your country, please contact your local Boston Scientific representative.

If IEC/EN 62353 is a required standard in your country, but no specific testing or interval is specified, it is recommended that you perform these safety tests using the direct method as specified in IEC/EN 62353 at an interval of every 24 months. Refer to the Specifications table ("Specifications" on page 40).

Service

For questions regarding operation or repair of the PRM or ZWT, contact Boston Scientific using the information on the back cover. The PRM and ZWT must be serviced by Boston Scientific personnel only.

If the PRM or ZWT malfunction and require repair, help to ensure efficient service by following these guidelines:

1. Leave the configuration of the instrument exactly as it was at the time of malfunction. Contact Boston Scientific using the information on the back cover.
2. Write a detailed description of the malfunction(s).
3. Save printouts or other materials that illustrate the problem.
4. If the PRM or ZWT must be returned to Boston Scientific for service, pack it in the shipping container in which it was received or in a shipping container provided by Boston Scientific.
5. For the shipping address, contact Boston Scientific using the information on the back cover.

For problems or questions that arise regarding operation or repair of the optional external printer, contact the printer manufacturer or agent.

HANDLING

Troubleshooting

If the PRM or ZWT does not operate properly, check that electrical cords and cables are securely connected and that cords and cables are in good working order (i.e., free of visible defects). Possible causes and corrective actions for problems are shown below. For external printer problems, refer to the manual for the external printer.

Table 2. Possible causes and corrective actions for PRM problems

Symptom	Possible Cause	Corrective Action
Internal printer/recorder does not function	No AC line voltage	Check that the power cord is plugged securely into the rear panel of the PRM. Change to a different electrical outlet.
	Paper jam	Open the printer door and use clean fingertips to both remove the paper and rotate the roller in a clockwise direction.
	No paper	Add paper.
Internal printer/recorder: paper-feed problems	Paper misaligned	Reload paper.
	Paper-feed obstruction	Clear obstruction from around the paper supply.

Table 2. Possible causes and corrective actions for PRM problems (continued)

Symptom	Possible Cause	Corrective Action
Internal printer/recorder: no print visible	Paper loaded upside down	Reload paper.
Internal printer/record: printing stops	Application did not handle print request	If the touchscreen is not responsive, turn off the PRM. Turn on the PRM and try printing any incomplete items again.
External printer does not function	No paper; paper jam; printer door open; toner cartridge not installed properly; printer power not On; printer not connected	Consult the manual for the external printer to determine the issue and corrective action.
Patient data disk error	Using disk created for a previous model of PRM or unformatted floppy disk	Use only the Patient Data Disk.
	Write-protect tab open	Close the write-protect tab.
Noise problems: ECG	Improper patient connections	Recheck patient leads for adequate skin contact and correct limb lead placement.
	Excessive radio emissions from equipment	Check surrounding area for electrical equipment that is powered on and not needed. Move unneeded equipment away from patient and/or PRM, or turn off unneeded equipment. Consult ECG textbooks for additional ECG techniques. Check for building-outlet ground resistance less than 10 Ω, when measured with low impedance techniques, between the outlets and from the outlets to other grounded points in the room (e.g., room bonding point, cold-water pipe, exam table, etc.).
Telemetry: no communication	Incorrect application software or incorrect PRM for pulse generator	Install proper application software for pulse generator in use.
	Incomplete telemetry communication	Reposition wand over the pulse generator; repeat interrogation.

Table 2. Possible causes and corrective actions for PRM problems (continued)

Symptom	Possible Cause	Corrective Action
Telemetry: intermittent communication	Incorrect telemetry wand	Use only the Model 6577 Sterilizable Telemetry Wand.
	Excessive radio emissions from equipment	Reorient the PRM antenna (if approved for use) or reposition the PRM. Also see Noise problems: ECG.
	Incomplete telemetry communication	Reposition wand over the pulse generator; repeat interrogation. Flip over wand; repeat interrogation. Disconnect and reconnect the wand; repeat interrogation. Turn off the PRM, and then turn on the PRM; repeat interrogation. Use another Model 3120 PRM; repeat interrogation. If this does not correct the issue, contact Boston Scientific using the information on the back cover.
Telemetry: interference	Harmful interference caused by the PRM or the PRM is negatively impacted by other RF devices	Reorient or relocate the devices.
		Increase the separation between the devices.
		Connect the equipment to an outlet on a different circuit.
		Contact Boston Scientific using the information on the back cover.
Missing shock markers during the delivery of a shock	Noise during shock delivery may prevent the shock marker from being received at the maximum telemetry distance of 6 cm (2.35 in)	Review surface ECG for confirmation of delivered shock. Review pulse generator's Arrhythmia Logbook for confirmation of delivered shock.
Displayed clock does not consistently keep time after setting	Low battery	Return the PRM to Boston Scientific for replacement of clock battery.
Touchscreen does not respond	Selecting inactive buttons on the touchscreen	Select active buttons.
	Touchscreen not functioning	Turn off the PRM, and then turn on the PRM. If this does not correct the issue, contact Boston Scientific using the information on the back cover.
Screen goes blank	Screen not functioning	
PRM not responding	PRM not functioning	

Table 3. Possible causes and corrective actions for ZWT problems

Symptom	Possible Cause	Corrective Action
Green indicator light on ZWT does not light within 60 seconds of powering on PRM	USB cable not securely connected to ZWT	Remove and reconnect both ends of USB Cable.
	USB cable damaged	Replace with Model 3141 USB Cable only.
	ZWT fault	Contact Boston Scientific using the information on the back cover.
Telemetry: intermittent communication	Telemetry RF signal obstructed	Assure that a clear line-of-sight path exists between ZWT and pulse generator. Repeat interrogation.
	Telemetry RF signal interference	Reposition or reorient ZWT at least 7.6 cm (3 in) or further from the PRM. Repeat interrogation.
	USB cable not securely connected to ZWT and PRM	Remove and reconnect both ends of USB cable. Reposition wand over the pulse generator and repeat interrogation.
	RF Telemetry fails	Reposition wand over pulse generator and repeat interrogation.
	PRM software version not current	Contact Boston Scientific using the information on the back cover.
Telemetry: interference	Harmful interference caused by the ZWT or the ZWT is negatively impacted by other RF devices	Reorient or relocate the devices.
		Increase the separation between the devices.
		Connect the equipment to an outlet on a different circuit.
		Contact Boston Scientific using the information on the back cover.

Using an External ECG Monitor with the PRM

Use the following accessories to set up the configuration described in this section:

- Model 6750 Surface ECG Patient Cable
- Model 6629 ECG–BNC Slave Cable
- Model 6577 Sterilizable Telemetry Wand

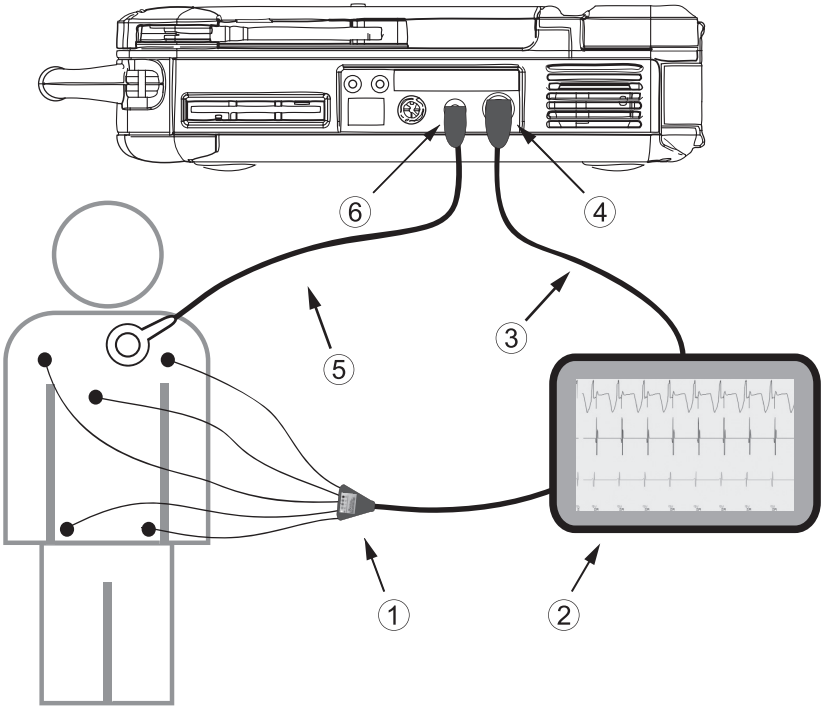


Figure 12. External ECG Monitor Configuration

To display a tracing on an external ECG monitor and the PRM, set up equipment as shown above (Figure 12 on page 31). In this example, the surface ECG travels via the ECG cable (1) to the external ECG monitor (2), then to the PRM via the ECG-BNC slave cable (3), connected to the PRM's ECG connector (4). Connect the telemetry wand (5) to the PRM's telemetry wand connector (6), ensuring that its cable does not cross any other cable.

Symbols on Packaging

The following symbols may be used on packaging and labeling (Table 4 on page 31):

Table 4. Symbols on packaging

Symbol	Description
REF	Reference number
SN	Serial number
	Use by

Table 4. Symbols on packaging (continued)

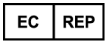
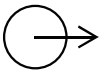
Symbol	Description
	Lot number
	Date of manufacture
	Non-ionizing electromagnetic radiation; ZIP telemetry indicator light
	Sterilized using ethylene oxide
	Consult instructions for use
	Follow instructions for use
	Temperature limitation
	Authorized Representative in the European Community
	Manufacturer
	Alternating current
	On/Off button
	USB
	Parallel connector for printer
	VGA output for external monitor
	Analog output
	Telemetry wand input and wanded telemetry indicator light

Table 4. Symbols on packaging (continued)

Symbol	Description
	Defibrillation-proof type CF applied part
	Defibrillation-proof type BF applied part
	ECG cable connector
	Paper form feed
	Calibration pulse
	Bring trace to baseline
	Indicates the potential equalization conductor. This connection allows a common ground with other equipment in a clinical setting.
	Mark for nationally recognized testing for safety standards
	RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.
	Attention: consult accompanying documents (ECG and Telemetry connectors)
	Port for authorized service use only
	Indicates the risk of electric shock; do not remove the cover (or back). Refer servicing to Boston Scientific.
	Waste, Electrical, and Electronic Equipment (WEEE). Indicates separate collection for electrical and electronic equipment (i.e., do not throw this device in the trash).

Table 4. Symbols on packaging (continued)

Symbol	Description
	On indicator light
	Assembly number
	This side up
	Fragile, handle with care
	Keep dry
	Do not use hooks
	Humidity limitations
	Atmospheric pressure limitations
	MR Unsafe

Environmental Protection and Disposal

Return the PRM and/or accessories to Boston Scientific at the end of their useful lives for appropriate disposal.

Compliance Standards

The following standards apply to the PRM.

Safety Standards

The PRM and ZWT have been tested and found to comply with applicable safety portions of the following standards:

- IEC 60601-1:2005 + C1:2006 + C2:2007 + INT1:2008 + INT2:2009
- ANSI/AAMI ES60601-1:2005 + C1:2009 + A2:2010
- BS EN 60601-1:2006 + C1:2006 + C2:2007 + C3:2010
- CAN/CSA-C22 No. 60601-1-08

Electromagnetic Compatibility Standards

The PRM has been tested and found to comply with the applicable portions of the electromagnetic compatibility (EMC) standards:

- FCC Part 15.209:2004 + 15.207:2004 + 15.249:2004
- EN 302 195-2 V1.1.1:2004
- EN 300 220-2 V2.1.2:2007
- EN 301 489-1 V1.8.1:2008
- EN 301 489-3 V1.4.1:2002

The ZWT has been tested and found to comply with the applicable portions of the electromagnetic compatibility (EMC) standards:

- EN 301 489–1 V1.9.2:2011
- EN 301 489–27 V1.1.1:2004
- EN 301 839–2 V1.3.1:2009
- IC RSS-243:2010

NOTE:

Use special precautions regarding EMC during the installation and the use of the PRM and ZWT, according to the EMC instructions given throughout this manual. Refer to the details about the PRM and ZWT electromagnetic emissions and immunity (Table 5 on page 36, Table 6 on page 36).

NOTE:

Use caution when using RF portable and mobile equipment in close proximity to the PRM and ZWT. Refer to the details about the PRM and ZWT electromagnetic immunity (Table 7 on page 38, Table 8 on page 39).

IEC 60601-1-2:2007 Information

This equipment has been tested and found to comply with the applicable limits for medical devices to ANSI/AAMI/IEC 60601-1-2:2007 [or BS EN 60601-1-2:2007 + C1:2010 or Active Implantable Medical Device Directive 90/385/EEC]. This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.

Federal Communications Commission (FCC)

This device complies with Title 47, Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment.

Electromagnetic Emissions and Immunity

The electromagnetic emissions and immunity information is provided below.

Table 5. Guidance and manufacturer's declaration - electromagnetic emissions - for all equipment and systems

Emissions test	Compliance	Electromagnetic environment — guidance[a]
RF emissions (CISPR 11)	Group 1	The PRM and ZWT use RF energy only for their internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions (CISPR 11)	Class A	The PRM and ZWT are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	
Voltage fluctuations / flicker emissions (IEC 61000-3-2)	Complies	

a. The PRM and ZWT are intended for use in the electromagnetic environment specified in the table. The customer or the user should ensure they are used in such an environment.

Table 6. Guidance and manufacturer's declaration - electromagnetic immunity - for all equipment systems

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance[a]
Electrostatic discharge (ESD) (IEC 61000-4-2)	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst (IEC 61000-4-4)	±2 kV for power-supply lines ±1 kV for input/output lines	±2 kV for power-supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Table 6. Guidance and manufacturer's declaration - electromagnetic immunity - for all equipment systems (continued)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment — guidance[a]
Surge (IEC 61000-4-5)	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power-supply input lines (IEC 61000-4-11)	<5% U_T (>95% dip in U_T) for 0.5 cycle[b] 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5%U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PRM requires continued operation during power mains interruptions, it is recommended that the PRM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

a. The PRM and ZWT are intended for use in the electromagnetic environment specified in the table. The customer or the user should ensure they are used in such an environment.
b. U_T is the AC mains voltage prior to application of the test level.

Table 7. Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are not life supporting

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment[a] — guidance[b]
Conducted RF (IEC 61000-4-6) Radiated RF (IEC 61000–4-3)	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the PRM or ZWT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ (80 MHz to 800 MHz)[c] $d = 2.3 \sqrt{P}$ (800 MHz to 2.5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Table 7. Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are not life supporting (continued)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment[a] — guidance[b]
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[d] should be less than the compliance level in each frequency range.[e] Interference may occur in the vicinity of equipment marked with the following symbol:

a. The PRM and ZWT are intended for use in the electromagnetic environment specified in the table. The customer or the user should ensure they are used in such an environment.
b. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
c. At 80 MHz and 800 MHz, the higher frequency range applies.
d. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PRM and ZWT are used exceeds the applicable RF compliance level shown in the table, they should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PRM and ZWT.
e. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 8. Recommended separation distances between portable and mobile RF communications equipment, and the PRM / ZWT

Rated maximum output power of transmitter[b] [c] W	Separation distance according to frequency of transmitter[a] m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz[d] $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

Table 8. Recommended separation distances between portable and mobile RF communications equipment, and the PRM / ZWT (continued)

Rated maximum output power of transmitter[b] [c] W	Separation distance according to frequency of transmitter[a] m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz[d] $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
10	3.8	3.8	7.3
100	12	12	23

a. The PRM and ZWT are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters), the PRM, and ZWT as recommended in the table, according to the maximum output power of the communications equipment.
b. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
c. For transmitters rated at a maximum output power not listed in the table, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
d. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Specifications

Table 9. PRM Nominal Specifications

Characteristic	Nominal
Safety classification	PRM: Class I. ECG connection: Type BF, defibrillation-protected. Telemetry-wand connection: Type CF, defibrillation-protected Ingress protection rating: IPX0
Dimensions	47 cm (18.5 in) deep, 36.8 cm (14.5 in) wide, 12.1 cm (4.75 in) high
Weight (approximate)	9.8 kg (21.5 lb)
Power rating	100–120 V 60 Hz, 220–240 V 50 Hz, 3.8/1.9 A
Power cord	2.4 m (8 ft), 100–240 V. Reliable grounding is achieved only when equipment is connected to receptacle marked with “Hospital only” or “Hospital grade.”
Duty cycle	Continuous
Operating temperature	10°C to 35°C (50°F to 95°F)
Transport and storage temperature	-40°C to 70°C (-40°F to 158°F)
Operating humidity	25% to 90%

Table 9. PRM Nominal Specifications (continued)

Characteristic	Nominal
Transport and storage humidity	25% to 95%
Operating altitude	≤ 2000 m
Transport and storage atmospheric pressure	50 kPa to 106 kPa (7.252 psi to 15.374 psi)
External printer support	DB 25 parallel port connector
External VGA monitor support	DB 15 VGA port connector
Analog output	± 1 V output via seven-pin DIN connector
Battery type	DL 2450 or equivalent
ECG cable	3.9 m to 4.3 m (12.7 ft to 14.0 ft)
ECG performance	
Minimum amplitude detected	4.56 µV
Lead selection	I, II, III, aVR, aVL, aVF, V
Intrinsic ventricular rate display	30 bpm to 120 bpm ± 4 bpm on a three-beat average basis; 120 bpm to 240 bpm ± 8 bpm on a three-beat average basis
Input impedance	> 2.5 M Ω
Electrode offset tolerance	300 mV
Storage resolution	800 samples/sec, 4.56 µV
Filter settings	ON: 0.5 Hz to 25 Hz, ± 0.2 dB, with 50 and 60 Hz notch filters; OFF: 0.5 Hz to 70 Hz, ± 0.2 dB, flat response, without 50 and 60 Hz notch filters; 0.05 Hz to 100 Hz, + 0.2 dB/-3.0 dB, without 50 and 60 Hz notch filters
Gain settings	1, 2, 5, 10, 20 mm/mV ± 25%
Wanded telemetry	
Frequency band	Transmit: 50 kHz Receive: 0–100 kHz
Bandwidth	100 kHz
Modulation	OOK
Effective radiated power	-1.2 dBµV/m
ZIP telemetry (ISM)	
Frequency band	ISM (902 to 928 MHz)

Table 9. PRM Nominal Specifications (continued)

Characteristic	Nominal
Bandwidth	< 1 MHz
Modulation	ASK/OOK
Effective radiated power	-1.3 dBm
Internal printer	
Paper type	Thermosensitive
Paper width	110 mm (4 in)
Chart speed	10, 25, 50, 100 mm/sec
Electrical Safety Testing-Reference for testing according to the IEC 60601[b]	
Earth resistance	≤ 100 mΩ
Earth leakage current	≤ 5 mA Normal Condition (NC), ≤ 10 mA Single Fault Condition (SFC)
Patient leakage current wand	≤ 10 µA Normal Condition (NC) and ≤ 50 µA Single Fault Condition (SFC) (mains on applied parts)
Patient leakage current ECG	≤ 100 µA Normal Condition (NC), ≤ 500 µA Single Fault Condition (SFC) (mains on applied parts)
Electrical Safety Testing-Reference for testing according to the IEC 62353 (Installation, Maintenance, Repair)[ab]	
Earthbond testing (Groundbond testing)	≤ 300 mΩ including power cable not exceeding 3 meters
Equipment leakage — direct method	ECG (BF) and Wand (CF) : ≤ 500 µA
Patient leakage current — direct method	ECG (BF) ≤ 500 µA, Wand (CF): ≤ 50 µA
Safety Features	
Defibrillator protection	to 5000 V 400 J

a. For questions regarding operation or repair of the PRM, contact Boston Scientific using the information on the back cover. The PRM must be serviced by Boston Scientific personnel only.
b. After successfully completing safety testing, verify the PRM continues to meet the essential performance as defined in the beginning of this manual.

Table 10. ZWT Nominal Specifications

Characteristic	Nominal
Safety classification	Ingress protection rating: IPX0
Dimensions	17.6 cm (6.9 in) wide, 17.3 cm (6.8 in) high, 4.6 cm (3 in) deep

Table 10. ZWT Nominal Specifications (continued)

Characteristic	Nominal
Weight (approximate)	0.6 kg (1.3 lb)
Power rating	5 V DC
Power cord	Power supplied via USB data cable
Duty cycle	Continuous
Operating temperature	10°C to 35°C (50°F to 95°F)
Transport and storage temperature	-40°C to 70°C (-40°F to 158°F)
Operating humidity	25% to 90%
Transport and storage humidity	25% to 95%
Operating altitude	≤ 2000 m
Transport and storage atmospheric pressure	50 kPa to 106 kPa (7.252 psi to 15.374 psi)
ZIP telemetry (MICS/MedRadio)	
Frequency Band	402–405 MHz Medical Implant Communication Service (MICS) Medical Device Radiocommunication Service (MedRadio)
Bandwidth	< 300 KHz
Modulation	FSK
Effective radiated power	22.4 µW (-16.5 dBm)

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DISCARD WITH ELECTRONIC WASTE